UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Hon. Patti B. Saris
THIS DOCUMENT RELATES TO: CLASS 1 JURY TRIAL (BMS)	

BMS'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE
TESTIMONY AND EVIDENCE CONCERNING AGGREGATE DAMAGES

Defendants Bristol-Myers Squibb Company and Oncology Therapeutics Network Corporation (collectively, "BMS") respectfully submit this memorandum of law in support of their motion in limine, pursuant to Federal Rules of Evidence 402 and 403 and Federal Rules of Civil Procedure 16, 23 and 37, for an Order excluding from evidence at trial documents and testimony relating to plaintiffs' calculation of aggregate class-wide damages.[1]

[1] BMS and the other Track 1 defendants previously moved to preclude Dr. Raymond Hartman's Class 1-related testimony under Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). (6/16/06 Track 1 Defs.' Mot. to Preclude the Expert Testimony of Dr. Raymond Hartman in Connection with Classes 1 and 2, or, in the Alternative, for a Daubert Hearing.) The Court has never ruled on this motion. The Court did deny the Track 1 Defendants' renewed Daubert motion with respect to Dr. Hartman's Class 2 and Class 3 testimony (1/19/07 Track 1 Defs.' Renewed Mot. to Strike the Expert Testimony of Dr. Raymond Hartman in Connection with the Trial of Class 2 and Class 3), which was provided in the context of a bench, not a jury, trial, where the Court indicated it would evaluate whether criticism under Daubert affected the weight of his testimony. Here, in the jury context, Daubert takes on added significance. Accordingly, BMS renews the request for a ruling with respect to the previously filed Daubert motion as to Dr. Hartman's Class 1 testimony. As set forth below, however, this motion seeks to exclude aggregate damages testimony and evidence for additional reasons that are independent of the already pending Daubert challenge to Dr. Hartman as it relates to Class 1.

Preliminary Statement

Plaintiffs intend to ask the jury to award a single, aggregate damage number based on the assumption that every class member has the same valid claim. There are three insurmountable problems with such an approach.

First, as BMS demonstrates in a separate memorandum relating to "multi-source drugs," many alleged class members will be unable to establish that they received and paid for the BMS version of such a drug and/or that they paid based on a median AWP for which BMS was responsible. Many of the 37 different state consumer protection laws at issue in this case (and the general common law fraud charge contemplated by the Court) require individual consumers to demonstrate injury and damages as a proximate cause of the defendant's conduct. Plaintiffs' proposed class-wide determination of damages -- divorced from individualized proof by class members of (a) receipt of a BMS drug, (b) collection by their doctor of a co-payment therefor and (c) that their co-payment was based on a BMS price (as opposed to the doctor's billed charge or some other price for which BMS was not responsible) -- is consequently highly inappropriate. Indeed, it impermissibly subjects BMS to greater liability than is permitted under consumer and common law fraud and alters its substantive rights in violation of due process.

Second, plaintiffs cannot "get around" this problem by focusing on BMS's sales data for its own version of the drugs in question because plaintiffs have no reliable way to show from that data how many "units" made their way to class members, let alone whether a patient's doctor actually collected the co-payment, whether the co-payment was based on the billed charges and not AWP, or whether recovery is barred by the applicable statute of limitations or other defenses. Plaintiffs' proposed aggregate damages calculations also fail to provide deductions for opt-outs or for those who, for a variety of reasons, will never submit a claim (or a

sufficient one). In short, plaintiffs' calculation of aggregate damages are so speculative as to be unreliable.

Third, permitting plaintiffs to adduce testimony on aggregate class-wide damages would be unfairly prejudicial to BMS because it will suggest that injury to the class was greater than it actually was. This may cause the jury to find liability where it might not otherwise exist. A better approach would be to permit the jury to decide on alleged damages "per unit" of a BMS drug, leaving quantification of the final aggregate damages amount to the claims process.

Argument

I.

TESTIMONY REGARDING HYPOTHETICAL AGGREGATE DAMAGES IS IMPERMISSIBLE

Where, as here, many of the 37 different state consumer protection statutes and the common law of fraud require a showing that the Class member did, in fact, sustain injury and damages, the "fact of damage" is an essential element of the claim.[2] In this case, many of the claims at issue are for "multi-source" drugs manufactured by both BMS and several other competitors. Most Class members will be unable to show which manufacturer's drug they were given and paid for. Even if they could, since BMS's version of a drug was often the "brand," the AWP on the BMS version could not have driven the median reimbursement rate since, as a matter of regulation, (i) the brand AWP was, prior to 1998, excluded from the calculation of the reimbursement rate and (ii) thereafter, was only one price to be used in calculating the median.

[2] See, e.g., Wallis v. Ford Motor Co., 208 S.W.3d 153, 161-62 (Ark. 2005) ("Once again, the ADTPA only allows a private cause of action to recover 'actual damage or injury.'") (quoting Ark. Code Ann. § 4-88-113(f)); Ziglin v. Players MH, L.P., 36 S.W.3d 786, 790 (Mo. Ct. App. 2001) ("The language of this section is plain and unambiguous. . . . A private cause of action is given only to one who purchases and suffers damage.") (internal quotations and citation omitted)); Peery v. Hansen, 585 P.2d 574, 577 (Ariz. Ct. App. 1978) ("It is clear that before a private party may exert a claim under the [consumer protection] statute, he must have been damaged by the prohibited practice.").

Any aggregate damages award that is not tied to individualized proof of actual payments by Class members for a BMS drug made on the basis of an AWP for which BMS was responsible, is improper and should be disallowed. Put differently, where "the very fact of injury, apart from the amount of damages, depends almost entirely on individual circumstances," a class-wide determination of damages is inappropriate. Lester v. Percudani, 217 F.R.D. 345, 352 (M.D. Pa. 2003) ("The issue of damages, a prerequisite of claims under both RICO and the Pennsylvania [Unfair Trade Practices and Consumer Protection Law], presents the court with the prospect of holding hundreds or thousands of individual hearings."); see also Andrews v. Am. Tel. & Tel. Co., 95 F.3d 1014, 1025 (11th Cir. 1996) (noting that "problems with trying the individualized elements of the plaintiffs' claims, as well as handling the unique aspects of the 900-number programs, are compounded by the necessity of referencing fifty sets of credit card and consumer protection laws"); Bell Atl. Corp. v. AT&T Corp., 339 F.3d 294 (5th Cir. 2003) (same in antitrust context).[3]

II.

PLAINTIFFS' METHODOLOGY OF AGGREGATE DAMAGES IS IMPROPERLY INFLATED

Plaintiffs seek to avoid the problem of Class members' inability to establish which version of a multi-source drug they received by using BMS's own sales data for the drug.

[3] See also Cimino v. Raymark Indus., Inc., 151 F.3d 297, 312 (5th Cir. 1998) ("Substantive law [here Texas law] includes not only the factual elements which must be found to impose liability and fix damages, but also the burdens of going forward with evidence and of persuasion thereon. . . . None of the foregoing is or can be altered by the utilization of Fed. R. Civ. P. 23(b)(3) . . . ."); Kline v. Coldwell, Banker & Co., 508 F.2d 226, 236 & n.8 (9th Cir. 1974) ("It has been suggested that generalized proof of damages might suffice under Rule 23. But the rule does not eliminate the ultimate need for individual proof of damages by each member of the class. Nor does it foreclose the right of each defendant to assert his defenses before a jury if one is requested."); Sample v. Monsanto Co., 218 F.R.D. 644, 650 (E.D. Mo. 2003) (rejecting plaintiffs' presumption of "class-wide impact without any consideration of whether the markets or the alleged conspiracy at issue here actually operated in such a manner so as to justify that presumption," noting that the expert "assumes the answer to this critical issue and plaintiffs, in turn, have asked the Court to rely on this conclusion as support for class certification").

The fundamental flaw in this approach is that the data in no way permits plaintiffs reliably to estimate the extent to which BMS drugs made their way to Class members.

Briefly, plaintiffs' expert Dr. Hartman tries to estimate the number of units that make their way to Class members by (a) estimating the number of units sold to doctors, nursing homes and other non-hospital, non-governmental medical providers and (b) using a government survey called NAMCS to come up with an alleged percentage of these units for which the providers were reimbursed by Medicare. The first assumption undoubtedly overstates the number of units "in" the class; the second is – on the face of the survey – unreliable.[4]

NAMCS is an annual survey of physicians in which they report for a particular medical procedure, among other things, the primary payor for reimbursement purposes. For example, an oncologist might report administering Rubex (doxorubicin hcl) to a patient and whether he or she billed Medicare or a commercial insurance carrier.

The problem for Dr. Hartman and plaintiffs is that the NAMCS data is so sparse as to be unreliable for this purpose. In the case of Rubex, there are only 2 years in the entire 10-year period (1993-2002) that Dr. Hartman analyzed in which any doctor in the survey claimed to have administered doxorubicin hcl. Even in those two years, there were only 4 "records" (i.e. survey responses) in 1999 and 1 in 2001: a total of 5 records over 10 years out of which only 2 indicate Medicare as the payor. Dr. Hartman tenuously concludes from this very small sample

[4] This methodology also suffers from several of the same problems discussed above. Plaintiffs' expert fails to account for other various prerequisites to recovery, such as whether a Class member's recovery is barred by the state statute of limitations; or precluded because his or her doctor did not actually collect the co-payment, or he or she paid a co-payment based on the doctor's billed charges, or a median AWP not influenced by BMS. Further, Dr. Hartman simply ignores those consumers who have opted out of the class and those consumers who, for a variety of reasons, will never submit a claim (or a sufficient one) (see, e.g., 9/12/06 Mot. Hr'g Tr. 15-16 (plaintiffs' counsel noting that, as far as consumer claimants to the GSK Settlement are concerned, he expects 10 percent or "something in the teens, even with individual notice" to actually submit a claim). Plaintiffs have reported that 23,000 consumers have opted out of the Class. (3/29/07 Pls.' Mot. for Approval of Further Commc'ns with Class 1 Consumers 1.) Although counsel for AstraZeneca requested that plaintiffs produce the names of the consumers who have opted out of Class 1, BMS understands that plaintiffs have refused to disclose any information concerning these consumers.

that, every year from 1991 to 2004 (i.e. including for all years in which he has no NAMCS data whatsoever), a weighted share of 26.44% of BMS's sales of Rubex to physicians (i.e. after deducting sales to hospitals and to government) were reimbursed through Medicare. Dr. Hartman ignores the fact that any conclusions from such a small sample cannot be statistically significant; that is, they cannot be considered to be reliable.

Under the heading "Reliability of Survey Estimates," the National Center for Health Statistics ("NCHS") describes what Dr. Hartman is doing as "unreliable" given the paucity of records. The Center's website states as follows:

> The standard error of an estimate is primarily a measure of the sampling variability that occurs by chance because only a sample is surveyed, rather than the entire universe. Because the NHAMCS is a sample survey, users should be aware of the reliability or unreliability of survey estimates, particularly the smaller estimates. NCHS considers an estimate to be reliable if it has a relative standard error of 30 percent or less (that is, the standard error is no more than 30 percent of the estimate). It should be noted, too, that estimates based on fewer than 30 records are also considered unreliable, regardless of the magnitude of the relative standard error.

At http://www.cdc.gov/nchs/about/major/ahcd/ reliability.htm (last visited June 10, 2007) (emphasis added).

According to the NAMCS data cited by Dr. Hartman (enclosed herewith as Ex. A), *there is not a single BMS Subject Drug that has 30 records in a year*. Not only Rubex, but other BMS drugs like Vepesid and Paraplatin show years in which there are no records in the NAMCS data. Indeed, even if one added all ten of the years for which Dr. Hartman examines these data, there would be fewer than 30 records for Vepesid and Rubex and only 30 total for Paraplatin.

The errors in Dr. Hartman's methodology are compounded when one realizes that the alleged "spreads" on the BMS Subject Drugs can vary dramatically from year to year,

making it critical to calculate accurately how many units of a drug, in which year, are actually being reimbursed by Medicare as opposed to some other payor. For example, the alleged spread on a 500mg vial of Vepesid increases from 33.9% in 1993 to 500.3% in 1997, but Dr. Hartman concludes – based on 4 records in 1993, 0 records in 1997 and a handful of records in other years – that in each and every year a weighted share of 42.97% of his calculated Vepesid sales to doctors were reimbursed by Medicare.

The law allows some flexibility in the method for calculating damages. Where, as here however, the "calculation of damages is not susceptible to a mathematical or formulaic calculation, or where the formula by which the parties propose to calculate individual damages is plainly inadequate," a determination of class-wide damages is improper. Corley v. Entergy Corp., 220 F.R.D. 478, 485 (E.D. Tex. 2004) (internal quotations omitted); see also Bell Atl. Corp., 339 F.3d at 302; Piggly Wiggly Clarksville, Inc. v. Interstate Brands Corp., 215 F.R.D. 523, 528 (E.D. Tex. 2003), aff'd, 100 Fed. Appx. 296 (5th Cir. 2004) (unpublished opinion). As the Eleventh Circuit has observed, aggregate damages awards are inappropriate where individualized proof of claims pose significant obstacles to the accurate calculation of class-wide damages. See Allapattah Servs., Inc. v. Exxon Corp., 333 F.3d 1248, 1257 (11th Cir. 2003) ("[T]he determination of the amount that each dealer was overcharged during the class period must take place on an individual basis . . . . [T]he considerations that must be taken into account to calculate the correct amount of damages during the claims process reveal the obstacles to entering an aggregate judgment for the class."). Such obstacles may include, as noted in Allapattah:

> (1) accounting for those . . . who either have opted out of the class or not submitted claims; (2) accounting for those . . . whose claims were barred by the [state] statute[s] of limitations; (3) the difficulty of awarding prejudgment interest on a class-wide basis when the applicable amount of interest varies from state to

> state; and (4) determining whether the [Class member's] claims are subject to further reduction by set-off claims asserted by [defendant].

Id.; see also Cont'l Orthopedic Appliances, Inc. v. Health Ins. Plan of Greater N.Y., 198 F.R.D. 41, 47-48 (E.D.N.Y. 2000) (noting that class-wide adjudication of damages improper where, *inter alia*, defendants intended to introduce evidence that some plaintiffs never attempted to mitigate their damages). Importantly, it is improper for an expert to "focus[] . . . on a fictional typical [plaintiff]" rather than attempt to calculate damages sustained by an actual class member. Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 343 (4th Cir. 1998) ("Plaintiffs attempted to substitute this 'hypothetical or speculative' evidence, divorced from any actual proof of damages, for the proof of individual damages necessary to meet North Carolina's 'reasonable certainty' standard of proof for lost profits awards. That this shortcut was necessary in order for this suit to proceed as a class action should have been a caution signal to the district court that class-wide proof of damages was impermissible.") (citation omitted); see also Sikes v. Teledyne, Inc., 281 F.3d 1350, 1366 (11th Cir. 2002) ("These claims will involve extensive individualized inquiries on the issues of injury and damages—so much so that a class action is not sustainable. The district court presumably recognized this or it would not have employed a presumption on these issues to avoid having to decertify the class. We cannot condone the use of a presumption as a 'shortcut' in resolving issues of injury and damages where such elements are provable by the plaintiffs and are required for recovery.").

Finally, this fundamental problem cannot be cured at some later date through a fluid recovery (or cy pres) mechanism. The problem is not how the damages should be allocated (where fluid recovery may be appropriate), but whether the aggregate damages contemplated are proper. Courts have long observed that fluid recovery may not be permitted to subject a defendant to greater liability or to alter its substantive rights. See, e.g., Windham v. Am. Brands,

Inc., 565 F.2d 59 (4th Cir. 1977); Van Gemert v. Boeing Co., 553 F.2d 812 (2d Cir. 1977); In re Hotel Tel. Charges, 500 F.2d 86 (9th Cir. 1974); Eisen v. Carlisle & Jacquelin, 479 F.2d 1005 (2d Cir. 1973), vacated on other grounds, 417 U.S. 156 (1974); Dumas v. Albers Med., Inc., No. 03-0640-CV-W-GAF, 2005 WL 2172030 (W.D. Mo. Sept. 7, 2005). Indeed, such impermissible use of a fluid recovery mechanism raises questions of constitutional dimension. See, e.g., Eisen, 479 F.2d at 1018 ("Even if amended Rule 23 could be read . . . to permit any such fantastic procedure, the courts would have to reject it as an unconstitutional violation of the requirement of due process of law."); see also Parker v. Time Warner Entm't Co., 331 F.3d 13, 22 (2d Cir. 2003) ("It may be that the aggregation in a class action of large numbers of statutory damages claims potentially distorts the purpose of both statutory damages and class actions. If so, such a distortion could create a potentially enormous aggregate recovery for plaintiffs, and thus an *in terrorem* effect on defendants, which may induce unfair settlements. And it may be that in a sufficiently serious case the due process clause might be invoked, not to prevent certification, but to nullify that effect and reduce the aggregate damage award.").

Further, use of fluid recovery here could contravene the mandate of the Rules Enabling Act "that the Rules of Civil Procedure shall not abridge, enlarge or modify any substantive right." Windham, 565 F.2d at 66; see also In re Hotel Tel. Charges, 500 F.2d at 90 ("[A]llowing gross damages by treating unsubstantiated claims of class members collectively significantly alters substantive rights under the antitrust statutes. Such enlargement or modification of substantive statutory rights by procedural devices is clearly prohibited by the Enabling Act."); cf. In re Fibreboard Corp., 893 F.2d 706, 711-12 (5th Cir. 1990) (discussing these concerns, and vacating the consolidation of cases by the district court as working a change in the parties' substantive rights under Texas law in a manner barred by the Erie doctrine). This

may be so if not all of the state consumer protection statutes, pursuant to which Class 1 is certified, permit for fluid recovery.[5]

III.

PLAINTIFFS' PRESENTATION OF AGGREGATE DAMAGES WOULD BE UNFAIRLY PREJUDICIAL TO BMS AND WOULD RESULT IN CONFUSION OF THE ISSUES

Evidence of aggregate damages should also be excluded because "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed R. Evid. 403; cf. Kemper/Prime Indus. Partners v. Montgomery Watson Americas, Inc., No. 97 C 4278, 2004 WL 725223, at *5 n.3 (N.D. Ill. Mar. 31, 2004) (noting that "Plaintiffs' evidence of damages likely would not be admissible at trial because the probative value of that evidence is unquestionably outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury") (internal quotation marks omitted). First, presentation of damages figures (ranging from approximately $24,031,209 to approximately $ $30,494,154) (Hartman's BMS Report 46)[6] is unfairly prejudicial and misleading both because of the artificially inflated nature of these figures and because of the flaws underlying the calculations, resulting in the overstatement of monetary losses allegedly sustained by Class 1

[5] See, e.g., Oregon R. Civ. P. 32F(2); State ex rel. Nixon v. Am. Tobacco Co., Inc., No. ED 76054, 2000 WL 29421, at *12 (Mo. App. Jan. 18, 2000) ("To this court's knowledge, the cy pres doctrine has never been applied in [situations other than in the context of trust instruments] in Missouri. In the case at hand, we are [not dealing with] a charitable trust. As such, the cy pres doctrine has no applicability."), transferred, 34 S.W.3d 122 (Mo. 2000) (not addressing this issue); Reader v. Magma-Superior Copper Co., 515 P.2d 860, 862 (Ariz. 1973) ("In the instant case, we have concluded that this class is completely unmanageable because of the impossibility of distributing to the class without resorting to 'fluid recovery,' which has been stamped as improper by Eisen III. The instant case is even more difficult because of the vague and indefinite damage suffered, and the impossibility of the vast majority of the members of the class being able to put a value on their individual damages.").

[6] Through 2003, excluding interest.

beneficiaries.[7] Second, presentation of competing methodologies that produce different results, all of which are inaccurate, will inevitably lead to the confusion of the issues.

[7] Some of the variability in these figures is attributable to Dr. Hartman's inclusion of damages for 2004 in his aggregate damages. Damages allegedly incurred for transactions that occurred in 2004 are inadmissible as they are likely to cause jury confusion, in addition to being irrelevant under this Court's November 2, 2006 decision on summary judgment.

Conclusion

For the foregoing reasons, BMS respectfully requests that this Court exclude evidence concerning aggregate damages, and, in particular, preclude the testimony of Dr. Raymond S. Hartman in its entirety.

Dated: June 11, 2007

Respectfully Submitted,

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CERTIFICATE OF SERVICE BY LEXIS-NEXIS FILE & SERVE

I, Lyndon M. Tretter, hereby certify that I am one of Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp.'s attorneys and that, on June 11, 2007, I caused a copy of **BMS'S MOTION IN LIMINE TO EXCLUDE TESTIMONY AND EVIDENCE CONCERNING AGGREGATE DAMAGES** and **MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE TESTIMONY AND EVIDENCE CONCERNING AGGREGATE DAMAGES** to be served on all counsel of record by electronic service pursuant to Paragraph 11 of CMO No. 2 by sending a copy to Lexis-Nexis File & Serve for posting and notification to all parties.

/s/ Lyndon M. Tretter
Lyndon M. Tretter